

§ 37.96

(also called trials), as well as the FEV6 derived from those maneuvers reported.

(4) *Examination.* The spirometry examination will be conducted in accordance with test procedures defined in the 2005 ATS/ERS Standardisation of Spirometry, pp. 323-326, and the Standardisation of Lung Function Testing, Replies to Readers, pp. 1496-1498 (both incorporated by reference, see § 37.97).

(i) The technician must be able to view real-time testing display screens as specified in the 2005 ATS/ERS Standardisation of Spirometry, p. 322 (incorporated by reference, see § 37.97).

(ii) A miner will be tested in the standing position, but may be seated if he or she experiences lightheadedness or other signs or symptoms that raise a safety concern relating to the standing position during the spirometry test.

(d) *Submission of test results.* NIOSH-approved facilities must submit results of spirometry examinations electronically with content as specified in § 37.96(b), pre-test screening checklists, and standardized respiratory assessments within 14 calendar days of testing a miner.

(e) *Records retention.* On-site records of the results will include spirometry examination reports and retention of all spirometry examinations, pre-test checklists, and standardized respiratory assessment results in electronic or printed format until notification to delete or render the information inaccessible, as described in § 37.100(b)(6)(ii), is received from NIOSH.

§ 37.96 Spirometry interpretations, reports, and notifications.

(a) *Interpretation of spirometry examinations.* Interpretations will be carried out by physicians or other qualified health care professionals with expertise in spirometry who have all required licensure and privileges to provide this service in their State or Territory. Interpretations must be carried out using procedures and criteria consistent with recommendations in the ATS Technical Standards: Spirometry in the Occupational Setting, pp. 987-990, and the ATS/ERS Interpretative Strategies for Lung Function Tests, p.

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950, p. 956 including Table 5, and p. 957 including Table 6 (both incorporated by reference, see § 37.97).

(b) *Spirometry test reports at the facilities.* (1) Spirometry test reports must contain, at a minimum, the miner's age, height, gender, race, and weight, numerical values (FVC, FEV6, FEV1, FEV1/FVC, FEV1/FEV6, FET, and PEF) and volume-time and flow-volume spirograms for all recorded expiratory maneuvers, normal reference value set used, the predicted, percent predicted and lower limit of normal values, miner position during testing (standing or sitting), dates of test and last calibration check, ambient temperature and barometric pressure (volume spirometers), and the technician's unique identification number.

(2) NIOSH will notify the submitting facility when to permanently delete or, if this is not technologically feasible for the spirometry system used, render permanently inaccessible all files and forms associated with a miner's spirometry examination from its electronic and physical files.

(c) *Notifying miners of spirometry examination results.* (1) Findings must be communicated to the miner or, if requested by the miner, to the miner's designated physician. The health care professional at the NIOSH-approved facility must inform the miner if the spirometry examination shows abnormal results or if the respiratory assessment suggests he or she may benefit from the medical follow-up or a smoking cessation intervention.

(2) NIOSH will notify the miner of his or her spirometry examination results and the results of a comparison between current and previously submitted spirometry examinations and will advise the miner to contact a health care professional as appropriate based on the results.

(d) *Submission of results.* Each facility must submit spirometry results and completed forms to NIOSH within 14 days after a miner has received an examination under this subpart. If specified under a facility's approval, it must submit spirometry results and the completed Respiratory Assessment Form (Form CDC/NIOSH (M)2.13) and Spirometry Notification Form (Form CDC/NIOSH (M)2.16), available at <http://>

www.cdc.gov/niosh/topics/surveillance/ords/

[CoalWorkersHealthSurvProgram.html](http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html), via electronic transmission. Facilities must utilize a secure internet data transfer site specified by NIOSH. The transmitted spirometry data files must include a variable length record providing all parameters in the format, content, and data structure described by the 2005 ATS/ERS Standardisation of Spirometry, p. 335 including Table 8 (incorporated by reference, see §37.97), or an alternate data file that is approved by NIOSH. If electronic transmission of spirometry results is not possible, for example if a facility's spirometer does not provide an approved electronic transfer of spirometry files, then the miner's Spirometry Results Form (Form CDC/NIOSH (M)2.17), available at <http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html>, must be completed and submitted accompanied by image files documenting the flow-volume and volume time curves for each trial reported on the Results Form. Such facilities must also send a completed Respiratory Assessment Form (Form CDC/NIOSH (M)2.13) and Spirometry Notification Form (Form CDC/NIOSH (M)2.16). Data submission to NIOSH by such a facility must be carried out as specified in the facility's approval.

(e) *Confidentiality of spirometry examinations.* Individual medical information and spirometry results are considered protected health information under HIPAA and may only be released as specified by HIPAA or to NIOSH as specified in §§37.93 and 37.96 of this subpart. Personally identifiable information in the possession of NIOSH will be released only with the written consent of the miner or, if the miner is deceased, the written consent of the miner's next of kin or legal representative. To provide on-site back-up and assure complete data transfer, facilities will retain the forms and results (in electronic or paper format) from a miner's examination until instruction has been received from NIOSH to delete the associated files and forms or, if this is not technologically feasible, render the data permanently inaccessible.

§ 37.97 Standards incorporated by reference.

(a) Certain material is incorporated by reference into this subpart, Subpart—Spirometry Examinations, with the approval of the Director of the FEDERAL REGISTER under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, NIOSH must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at NIOSH, Division of Respiratory Disease Studies, 1095 Willowdale Road, Morgantown, WV 26505. To arrange for an inspection at NIOSH, call 304-285-5749. Copies are also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibv_locations.html.

(b) American Journal of Respiratory and Critical Care Medicine, American Thoracic Society (ATS), 25 Broadway, 18th Floor, New York, NY 10004. Phone: (800) 635-7181, extension 8065. Email: Hope.Robinson@sheridan.com. <http://www.atsjournals.org/action/showHome>:

(1) Standardization of Spirometry; 1994 Update. Official Statement of the ATS, adopted November 11, 1994. American Journal of Respiratory and Critical Care Medicine 152(3):1107-1136, September 1995, into §37.95(b). This ATS Official Statement is also available at <http://www.thoracic.org/statements/resources/archive/201.pdf>.

(2) Official American Thoracic Society Technical Standards: Spirometry in the Occupational Setting ("ATS Technical Standards: Spirometry in the Occupational Setting"). Redlich CA, Tarlo SM, Hankinson JL, Townsend MC, Eschenbacher WL, Von Essen SG, Sigsgaard T, and Weissman DN. American Journal of Respiratory and Critical Care Medicine 189(8):983-994, April 15, 2014, into §§37.92(b) and 37.96(a).

(3) Spirometric Reference Values from a Sample of the General U.S. Population. Hankinson JL, Odencrantz JR, Fedan KB. American Journal of Respiratory and Critical Care Medicine,